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(71) Applicant *(for all designated States except US)*: **SUNSHINE HEART COMPANY PTY LTD** [AU/AU]; 2A River Street, Birchgrove, NSW 2041 (AU).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **PETERS, William, Suttle** [NZ/NZ]; 93 Bassett Road, Remuera, Auckland 1005 (NZ).

(74) Agent: **SPRUSON & FERGUSON**; GPO Box 38988, Sydney, NSW 2001 (AU).

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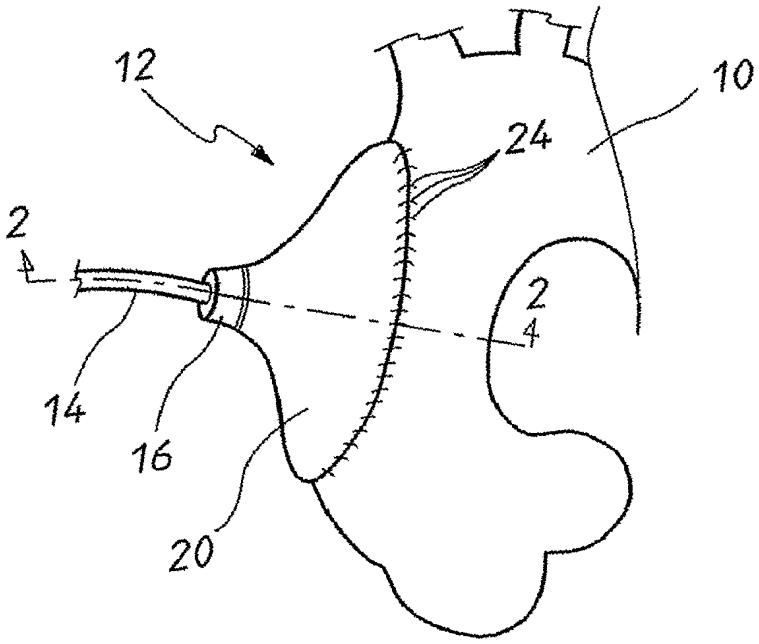
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: EXTRA-AORTIC PATCH



(57) Abstract: A method of heart assistance including the step of directly attaching a heart assist device (12) including an inflatable balloon or chamber (18) to, the exterior of an arterial vessel (10).

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EXTRA-AORTIC PATCH

Field of the Invention

The present invention relates generally to a counter-pulsation heart assist device, system and method and, more particularly, to an extra-aortic patch and a heart assist device and method using aortic deformation.

Background of the Invention

The Applicant's International PCT Patent Application Nos. PCT/AU00/00654 and PCT/AU02/00974 disclose various counter-pulsation heart assist devices that utilise aortic deformation. The contents of these specifications are hereby incorporated herein by cross reference.

Known counter-pulsation heart assist devices generally include an inelastic shell with a flexible membrane sealingly attached to the periphery of the shell. The membrane defines an inflatable space between it and the interior of the shell. The shell also has an inlet/outlet port which is adapted for connection to a motive means that can periodically introduce, and withdraw, a fluid to and from the space in counter-pulsation with the patient's heart rhythm. A substantially inelastic, flexible wrap is placed around an arterial vessel and over the device to secure the device adjacent the exterior of the vessel. The balloon is normally positioned on the radially outer side of the ascending aorta.

It is the object of the present invention to provide an alternative means for securing a heart assist device adjacent an arterial vessel.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a method of heart assistance including the step of directly attaching a heart assist device including an inflatable balloon or chamber to the exterior of an arterial vessel.

In one embodiment, the balloon or chamber is itself attached to the arterial vessel.

In another embodiment, a shroud forming a part of the heart assist device and overlying the balloon or chamber is attached to the vessel to hold the balloon or chamber in contact with the vessel. The shroud or the balloon or chamber is preferably attached to the aorta around its circumferential periphery.

In one embodiment, the method includes the step of directly attaching the shroud of the heart assist device to an arterial vessel with the associated inflatable balloon or chamber secured beneath the shroud and adjacent the vessel.

The method preferably includes suturing the shroud to the vessel, most preferably with non-absorbable sutures, unless the device is intended to be removed remotely at a latter date. Alternatively, the shroud can be glued to the vessel. As a further alternative, the shroud can be stapled or clipped to the vessel.

The balloon or chamber is preferably attached at substantially all of its surface exterior that is disposed adjacent to the vessel exterior.

In another embodiment, the method includes the step of directly attaching the balloon or chamber of the heart assist device to an arterial vessel with an associated shroud or wrap secured over the balloon or chamber and onto the vessel.

The method preferably includes gluing the balloon or chamber to the vessel, most preferably with fibrin or another natural adhesive protein.

The method preferably includes the step of sequentially introducing and withdrawing a fluid into and from the balloon or chamber in counterpulsation with the arterial vessel so as to bring about the heart assistance.

In a second aspect, the present invention provides a heart assist device including a shroud or wrap and an inflatable balloon or chamber, wherein the shroud or wrap has a larger peripheral extent than that of the balloon or chamber, and at least some of the periphery of the shroud or wrap is adapted for direct attachment to the arterial vessel.

The shroud periphery is preferably suturable to the vessel. The sutures are preferably non-absorbable. If the balloon is positioned over the descending thoracic aorta, the shroud periphery is sutured to the intercostal fascia and fascia overlying the vertebral column.

In another form, the shroud periphery is adapted for gluing to the vessel.

As a further alternative, the shroud periphery is adapted for stapling or clipping to the vessel.

In a third aspect, the present invention provides a method of heart assistance, the method including the steps of gluing an inflatable balloon or chamber of a heart assist device to a wall of an arterial vessel and inflating the balloon or chamber to cause inward displacement of the wall in the region that is adjacent the balloon or chamber.

Brief Description of the Drawings

A preferred embodiment of the invention will now be described, by way of an example only, with reference to the accompanying drawings in which:

Fig. 1 is a schematic perspective view of an aorta of a patient with a first embodiment of a device according to the invention attached thereto;

Fig. 2 is a schematic cross section view of the aorta and device shown in Fig. 1 along line 2-2; and

Fig. 3 is a schematic cross section view of an aorta and a second embodiment of device according to the invention attached thereto.

Detailed Description of the Preferred Embodiments

Fig. 1 is a schematic perspective view of an ascending aorta 10 and a heart assist device 12 according to a first embodiment of the invention. The device 12 has a fluid tube 14 for connection to a motive power source (not shown), which sealingly engages a bushing 16. A flexible balloon membrane 18 (see Fig. 2) is sealingly attached to the bushing 16. The balloon 18 is formed from a polyurethane, polyurethane-silicone co-polymer, silicone, or similar material

The balloon 18 is protected by an inelastic, shroud 20, which snugly engages the bushing 16 and sealingly sandwiches the open end of the balloon 18 therebetween. The shroud 20 has a larger peripheral extent (ie. is wider) than the balloon 18. The balloon 18 defines an inflatable space 22. The shroud 20 can be formed in part of whole of polyurethane, polyurethane-silicone co-polymer, silicone, polyester, or similar materials.

The device 12 is secured on the radially outer side of the ascending aorta 10 by the shroud 20 being directly attached to the aorta 10 by one or two rows of non absorbable sutures 24 along the sides of the shroud 20. The sutures 24 are preferably of the mono-filament type, such as Prolene 3/0 (Trade Mark), but may be any nonabsorbable material.

In operation, the motive means periodically introduces, and withdraws, a fluid (e.g. a gas such as helium or air or a liquid such as a saline solution or an oil) to and from the space 22 in counter-pulsation with the patient's heart rhythm. When fluid is introduced into the space 22, the balloon 18 expands and the aorta's external wall is compressed and inwardly deformed until it is close to but not abutting the aorta's opposite interior wall. When fluid is withdrawn from the space 22, the balloon retracts to the

configuration shown in Fig. 2 and the aorta 10 returns to normal position allowing maximum blood flow therethrough.

Fig. 3 is a schematic cross-sectional view of an ascending aorta 10 and a heart assist device 30 according to a second embodiment of the invention. Like features to those of the first embodiment will be denoted with like reference numerals in relation to the second embodiment. The device 30 differs from the device 12 in that the balloon 18 is itself directly attached to the aorta 10 by glue at (darkened) region 32.

The advantages of the above devices include that they are relatively easier and safer to implant compared to known surgical procedures because they are not in the blood stream, and because the ascending aorta does not need to be completely mobilised free of the pulmonary artery. The second embodiment also allows for placement of aorto-coronary bypass grafts to the ascending aorta, separate from the device 30. Additionally, as the back part of the aorta is not attached to the device, the ascending aorta retains a majority of its anisotropic elastic nature which is important to minimise any loss of aortic compliance. Such devices may be particularly useful in patients having re-do surgery, where scar tissue may make complete mobilisation of the aorta from the pulmonary artery difficult. Additionally, redo patients may have patent aorto-coronary bypass grafts, that can be retained on the aorta. The devices described above also allows for growth and/or dilation of the aorta over time and as such may be suitable for use in younger patients where the aorta is smaller, more elastic and growing, or in patients who have been in severe heart failure and the ascending aorta is smaller than normal for any given age, due to chronically low cardiac output. The advantages of such a device and method on the descending aorta is that, due to presence of multiple side-branches, circumferential wrapping is not easily achieved, and "patch" attachment is more achievable. Further, with the descending thoracic aorta, a longer length is made available and thus a larger balloon can be used. Finally, the devices described above advantageously reduce the amount of foreign material introduced into a patient's body.

It would be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiment without departing from the spirit or scope of the invention as broadly described. For example, surgical glue could be used in place of the sutures.

CLAIMS:

1. A method of heart assistance including the step of directly attaching a heart assist device including an inflatable balloon or chamber to the exterior of an arterial vessel.

2. The method as claimed in claim 1, wherein the balloon or chamber is itself attached to the arterial vessel.

3. The method as claimed in claim 1, wherein a shroud forming a part of the heart assist device and overlying the balloon or chamber is attached to the vessel to hold the balloon or chamber in contact with the vessel.

4. The method as claimed in claim 1, 2, or 3, wherein the shroud or the balloon or chamber is attached to the aorta around its circumferential periphery.

5. The method as claimed in claim 3, wherein the method includes the step of directly attaching the shroud of the heart assist device to an arterial vessel with the associated inflatable balloon or chamber secured beneath the shroud and adjacent the vessel.

6. The method as claimed in claim 5, wherein the method includes suturing the shroud to the vessel.

7. The method as claimed in claim 6, wherein the method includes suturing the shroud to the vessel with non-absorbable sutures.

8. The method as claimed in claim 5, wherein the method includes gluing the shroud to the vessel.

9. The method as claimed in claim 5, wherein the method includes stapling the shroud to the vessel.

10. The method as claimed in claim 5, wherein the method includes clipping the shroud to the vessel.

11. The method as claimed in any one of claims 5 to 10, wherein the balloon or chamber is attached at substantially all of its surface exterior that is disposed adjacent to the vessel exterior.

12. The method as claimed in claim 1 or 2, wherein the method includes the step of directly attaching the balloon or chamber of the heart assist device to an arterial vessel with an associated shroud or wrap secured over the balloon or chamber and onto the vessel.

13. The method as claimed in claim 12, wherein the method includes gluing the balloon or chamber to the vessel.

14. The method as claimed in claim 1 or 2, wherein the method includes the step of

directly attaching the balloon or chamber of the heart assist device to an arterial vessel with an associated fibrin or another natural adhesive protein secured over the balloon or chamber and onto the vessel.

15. The method as claimed in any one of the preceding claims, wherein the method includes the step of sequentially introducing and withdrawing a fluid into and from the balloon or chamber in counterpulsation with the arterial vessel.

16. A heart assist device including a shroud or wrap and an inflatable balloon or chamber, wherein the shroud or wrap has a larger peripheral extent than that of the balloon or chamber, and at least some of the periphery of the shroud or wrap is adapted for direct attachment to the arterial vessel.

17. The device as claimed in claim 16, wherein the shroud periphery is adapted for suturing to the vessel.

18. The device as claimed in claim 17, wherein the shroud periphery is sutured to the intercostal fascia and fascia overlying the vertebral column.

19. The device as claimed in claim 16, wherein the shroud periphery is adapted for gluing to the vessel.

20. The method as claimed in claim 16, wherein the shroud periphery is adapted for stapling to the vessel.

21. The device as claimed in claim 16, wherein the shroud periphery is adapted for clipping to the vessel.

22. A method of heart assistance, the method including the steps of gluing an inflatable balloon or chamber of a heart assist device to a wall of an arterial vessel and inflating the balloon or chamber to cause inward displacement of the wall in the region that is adjacent the balloon or chamber.

1/1

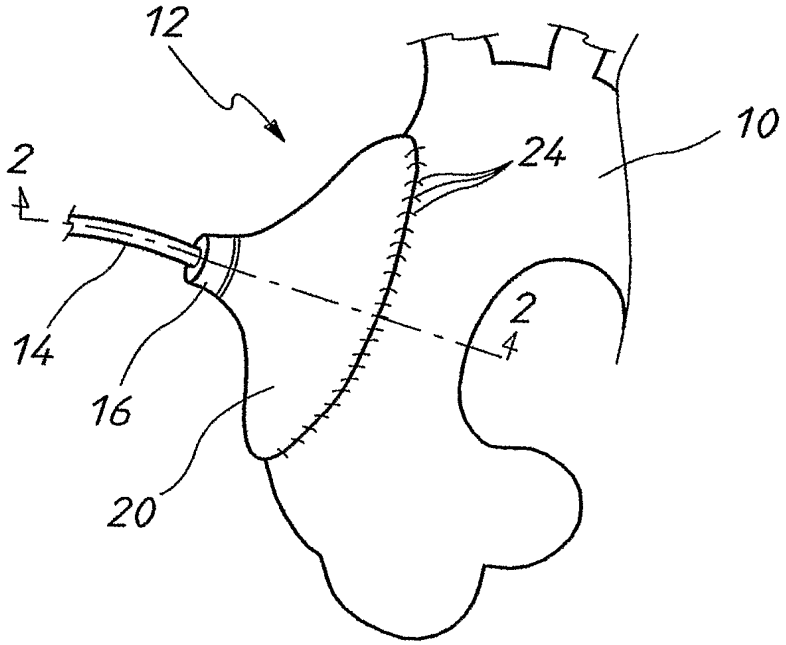

FIG. 1

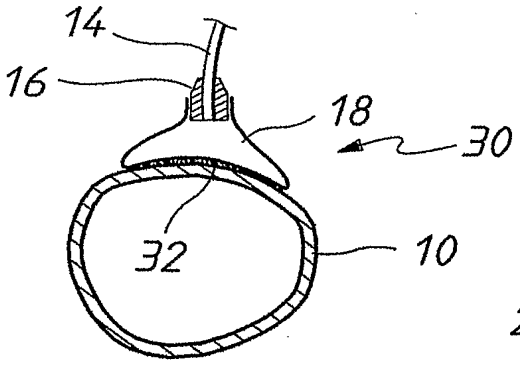

FIG. 3

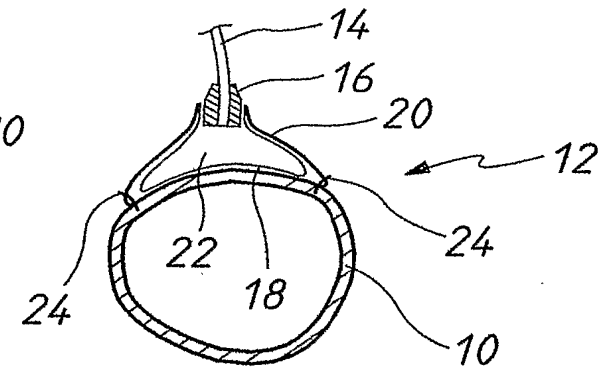

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001483

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI IPC A61M/- A61F/- A61B/- + keywords: (aort, heart, arter, balloon, inflat, assist, pump, pulsat, rhythm, attach, glue, suture, staple, clip, adhere)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2002/024254 A2 (IMPERIAL COLLEGE INNOVATIONS LIMITED) 28 March 2002 Pages 1-36	1-11, 15-22
X	WO 2002/024255 A1 (SUNSHINE HEART COMPANY PTY LTD) 28 March 2002 Pages 1-15	1-5, 15
X	WO 2000/076288 A2 (SUNSHINE HEART COMPANY PTY LTD) 21 December 2000 Pages 1-16	1-5, 7, 11, 15
A	Patent Abstracts of Japan, JP 10-328297 (BUAAYU:KK) 15 December 1998	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 November 2004	26 NOV 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Sue Thomas** Telephone No : (02) 6283 2454

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001483

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
JP	10328297	NIL					
WO	2000076288	AU	50548/00	BR	0011464	CA	2375962
		EP	1185319	US	2004167376		
WO	200224255	AU	91488/01	EP	1318848	US	2004073080
WO	200224254	AU	90088/01	BR	0114087	CA	2421812
		EP	1379294	US	2003233023		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX